

PCT

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## INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Article 36 and Rule 70)

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Applicant's or agent's file reference 2002.737. WO	<b>FOR FURTHER ACTION</b> See Notification of Transmittal of International Preliminary Examination Report (Form PCT/PEA416)	
International application No. PCT/EP 03/50627	International filing date (day/month/year) 17.09.2003	Priority date (day/month/year) 24.09.2002
International Patent Classification (IPC) or both national classification and IPC A61K9/20		
Applicant AKZO NOBEL N.V. et al.		

1. This international preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36.
2. This REPORT consists of a total of 5 sheets, including this cover sheet.
- ☒ This report is also accompanied by ANNEXES, i.e. sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT).

These annexes consist of a total of 1 sheets.

3. This report contains indications relating to the following items:

- I ☒ Basis of the opinion
- II ☐ Priority
- III ☐ Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
- IV ☐ Lack of unity of invention
- V ☒ Reasoned statement under Rule 66.2(a)(ii) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
- VI ☐ Certain documents cited
- VII ☐ Certain defects in the international application
- VIII ☐ Certain observations on the international application

Date of submission of the demand  15.03.2004	Date of completion of this report  31.08.2004
Name and mailing address of the international preliminary examining authority:  European Patent Office D-80298 Munich Tel. +49 89 2399 - 0 Tx: 523656 epmu d Fax: +49 89 2399 - 4465	Authorized Officer  Hedegaard, A  Telephone No. +49 89 2399-8644 

**INTERNATIONAL PRELIMINARY  
EXAMINATION REPORT**

International application No. **PCT/EP 03/50627**

**I. Basis of the report**

1. With regard to the **elements** of the international application (*Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report since they do not contain amendments (Rules 70.16 and 70.17)*):

**Description, Pages**

1-7 as originally filed

**Claims, Numbers**

1-6 as originally filed

2. With regard to the **language**, all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item.

These elements were available or furnished to this Authority in the following language: , which is:

- ☐ the language of a translation furnished for the purposes of the international search (under Rule 23.1(b)).
- ☐ the language of publication of the international application (under Rule 48.3(b)).
- ☐ the language of a translation furnished for the purposes of international preliminary examination (under Rule 55.2 and/or 55.3).

3. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, the international preliminary examination was carried out on the basis of the sequence listing:

- ☐ contained in the international application in written form.
- ☐ filed together with the international application in computer readable form.
- ☐ furnished subsequently to this Authority in written form.
- ☐ furnished subsequently to this Authority in computer readable form.
- ☐ The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.
- ☐ The statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished.

4. The amendments have resulted in the cancellation of:

- ☐ the description, pages:
- ☐ the claims, Nos.:
- ☐ the drawings, sheets:

5. ☐ This report has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed (Rule 70.2(c)).

*(Any replacement sheet containing such amendments must be referred to under item 1 and annexed to this report.)*

6. Additional observations, if necessary:

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EXAMINATION REPORT**

International application No. **PCT/EP 03/50627**

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**V. Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability;  
citations and explanations supporting such statement**

**1. Statement**

Novelty (N)	Yes: Claims	
	No: Claims	1-6
Inventive step (IS)	Yes: Claims	
	No: Claims	1-6
Industrial applicability (IA)	Yes: Claims	1-6
	No: Claims	

**2. Citations and explanations**

**see separate sheet**

**INTERNATIONAL PRELIMINARY  
EXAMINATION REPORT - SEPARATE SHEET**

International application No. PCT/EP 03/50627

**Re Section I**

**Basis of the opinion**

1. The feature "is maintained to have a water activity of at most 0.6" is not disclosed in the application as filed and is contrary to the provisions of Article 34(2)(b) PCT. Page 3, lines 11-15 of the application as filed only provides basis for the vague term "maintained at reduced level". Hence, this report has been established on the basis of the original wording "has a water activity of at most 0.6".

**Re Section V**

**Reasoned statement under Rule 66.2(a)(ii) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement**

1. Reference is made to the following documents:

D1: US-A-4 369 172  
D2: WO 02 45753 A  
D3: EP-A-0 700 680  
D4: GB-A-1 430 684  
D5: US-A-4 259 314

D1 discloses (see examples 1-4 in col. 4) tablets comprising 57% HPMC and a moisture content of 4.5-5.5%.

D2 discloses (see example 1 on p. 4-5) tablets comprising gepirone HCl (40, 60 or 80 mg) and 75% HPMC. The tablets are stored in tight containers.

D3 discloses (see claims 1, 3 and 14) tablets comprising gepirone HCl and 70-85% HPMC.

D4 discloses (see examples III-V)) tablets comprising more than 55% of Methocel. On p. 5, col. 1, l. 23-24 it is specified that the end product has a moisture content between 0.7 and 1.0%.

D5 discloses (see col. 4, l. 59 - col. 5, l. 9) dry formulations in the form of packed tablets having a matrix of HPMC with a moisture content of less than 1%.

2. The subject-matter of claim 1 is not novel (Art. 33(2) PCT) over D2 (see above under item 1). D2 does not mention the water activity, but "a water activity of at most 0.6" as defined in present claim 1 appears to be such a common feature (see e.g. D1, D4 and D5) that in carrying out the teaching of D2, the skilled person would inevitably arrive at a composition falling within the terms of present claim 1.

It is considered that the "tight containers" according to D2 do provide some protection against moisture (although less protection than e.g. hermetic containers). This is substantiated by the handbook (W. Jenkins and K. Osborn: "Packaging Drugs and Pharmaceuticals", 1993, p. 249-259) submitted by the Applicant with letter of 23.06.2004 where it can be seen (page 250, items 1 and 2) that tight containers (i) protect from vapors and (ii) have less moisture permeability than well-closed containers. Present claim 1 does not clearly define the delayed moisture uptake. The vague feature "such as to delay moisture uptake" in present claim 1 is too vague (Art. 6 PCT) to give a clear distinction over the (slightly) delayed moisture uptake due to tight containers in D2.

3. The problem of the present application was to reduce dust formation in tablets having a matrix consisting of at least 55% of a cellulose ether. This problem is solved by providing tablets having a water activity of at most 0.6 and packaging such as to delay moisture uptake by the tablet.

D1, which represent closest prior art, discloses tablets from which the subject-matter of claim 1 only differs in specifying that the tablet is packaged such as to delay moisture uptake by the tablet. However, for the skilled person it is a trivial feature to package tablets in order to protect the tablets, e.g. against damage or moisture, and consequently to avoid dust formation. Hence, the subject-matter of claim 1 is not considered to involve an inventive step (Art. 33(3) PCT).

The filing of a package as offered by the Applicant does not change the above-mentioned argumentation.

4. Having regard to the disclosures of D1-D4, dependent claims 2-6 do not appear to contain new and inventive features and are only allowable when related to an independent claim which fulfils the requirements of the PCT.